UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/083,357	02/27/2002	Qiandong Zeng	032796-090	3931

21839 7590 07/14/2004

BURNS DOANE SWECKER & MATHIS L L P
POST OFFICE BOX 1404
ALEXANDRIA, VA 22313-1404

EXAMINER	
AKHAVAN, RAMIN	
ART UNIT	**PAPER NUMBER**
1636	

DATE MAILED: 07/14/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/083,357	ZENG ET AL.	
	Examiner	Art Unit	
	Ramin (Ray) Akhavan	1636	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *1* MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *05 June 2002*.

2a)☐ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-59* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *1-59* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

Restriction to one of the following inventions is required under 35 U.S.C. 121; the groups are numbered as follows:

1. Claims 1-28, drawn to a method of identifying open reading frames (ORFs) in the genome of an organism, classified in class 707, subclass 1.
2. Claim 48, drawn to a method of inhibiting expression of a small open reading frame (smORF) using antisense, classified in class 435, subclass 6.
3. Claims 49-50, drawn to a method of identifying "inhibitory compounds to a protein", classified in class 435, subclass 7.1.
4. Claims 32-33, drawn to a vector and cells comprising the vector, classified in class 435, subclass 325.

5-795. Claim 29, 3-31, 34-35 and 58, drawn to smORFs of 790 distinct sequences, depicted in SEQ ID NOs: 1-119 and 674-1345, classified in class 536, subclass 23.1.

796-914. Claims 37 and 41-47, drawn to antisense molecules derived from 119 distinct sequences as depicted in SEQ ID NOs: 1-119, classified in class 536, subclass 24.5.

915-1585. Claims 38-40, 51-52 and 59, drawn to an isolated polypeptide from 671 distinct sequences, as well as the polypeptide as a pharmaceutical, classified in class 530, subclass 350.

1586-2256. Claims 53-56, drawn to antibodies, which recognize peptides encoded by 671 distinct sequences, classified in class 424, subclass 130.1.

Claims 1-59 encompass 2256 distinct inventions. Applicant must choose a single group for examination, notwithstanding traversal of this restriction requirement. For groups 5-914, this means electing a single SEQ ID NO for examination. This is not an election of species. The inventions presented can be broadly grouped into methods (Groups 1-3), vectors and cells comprising said vectors (Group 4), nucleic acid molecules (Groups 5-795), antisense molecules (796-914), polypeptides (Groups 915-1585) and antibodies (Groups 1586-2256).

The nucleic acid set, antisense molecule set and the protein set are distinct inventions based on unique structure to function correlations. A nucleic acid molecule drawn to a distinct structure (i.e. sequence) is biologically and patentably distinct from any other nucleic acid molecule. It logically follows, that any protein encoded by said sequences is also biologically and patentably distinct from any other protein. Furthermore, a protein shares no structure to function correlation as compared to nucleic acid molecules. In addition, nucleic acid molecules that are antisense molecules are distinct inventions as compared to the complementary nucleic acid molecules, because they inhere a specialized structure to function correlation not evident in the sequences against which they hybridize (i.e. encoding a protein versus conferring an inhibitory antisense effect). Considering the sequences claimed encode varying sized ORFs, which encode proteins of distinct functionality, it cannot be said that the presented sequences are interchangeable, thus species within a proper Markush group. Therefore, groups drawn to nucleic acid molecules or proteins molecules are distinguishable as amongst each other. In addition, the groups comprising the proteins are distinguishable as compared to groups comprising nucleic acid molecules. It further follows that groups drawn to distinct antibodies are each distinguishable as amongst each other and as compared to other sets, because of a separate

structure to functional correlation (i.e. recognizing a distinct polypeptide or polypeptide epitope). In sum, there is no structure to function correlation between the foregoing groups of nucleic acid molecules, polypeptides or antibodies.

The Inventions in the methods set (Groups 1-3) are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions. The methods presented are not necessarily capable of use together. Furthermore, each method inheres a specific mode of operation. For example, Group 2 requires steps necessary to inhibit protein expression, which simply would not be required in a method of genome analysis or a method of identification of "inhibitory compounds". Additionally, each group is directed to a distinct outcome or result.

Group 4 is a distinct invention, because a vector or cells comprising the vector, are not necessarily used in concert with any of the compositions (proteins, nucleic acids or antibodies) or in conjunction with the different methods. For example, the vector could be used in a hybridization assay, to transform cells for purposes of vector propagation or to knock out genes in cells, where the genes are not related to any of the articulated sequences.

With regard to the various compositions and methods, the same analysis applies whether the groups being assessed are proteins versus methods, nucleic acid molecules versus methods or antibodies versus methods. The relationship, where applicable, is one of product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of

using that product (MPEP § 806.05(h)). In the instant case the various nucleic acids could be used in a multitude of different processes (e.g. hybridization assay, gene knockout assay or gene amplification). Similarly, the various proteins can be used in distinct processes (e.g. two-hybrid assay). The various antibodies can be used in conjunction with liposomes for example, for cell targeting and delivery purposes.

Claims 31 links the inventions in the groups drawn to smORFs (i.e. Groups 5-795) represented by distinct sequences, SEQ ID NOs: 1-119 and 674-1345. Similarly, Claim 37 links the inventions in the groups drawn to antisense molecules (i.e. Groups 796-914) that hybdridize to sequences depicted in SEQ ID NOs: 1-119. The restriction requirement for the linked inventions is subject to the nonallowance of the linking claims, claims 31 and 37. Upon the allowance of the linking claims, the restriction requirement as to the linked inventions shall be withdrawn and any claim depending from or otherwise including all the limitations of the allowable linking claim will be entitled to examination in the instant application. Applicant is advised that if any such claim depending from or including all the limitations of the allowable linking claims is presented in a continuation or divisional application, the claims of the continuation or divisional application may be subject to provisional statutory and/or nonstatutory double patenting rejections over the claims of the instant application. Where a restriction requirement is withdrawn, the provisions of 35 U.S.C. 121 are no longer applicable. *In re Ziegler*, 44 F.2d 1211, 1215, 170 USPQ 129, 131-32 (CCPA 1971). See also MPEP § 804.01.

For the reasons given above these inventions are distinct and have acquired a separate status in the art as shown by their different classification. In addition each group would require a separate search, thus restriction for examination purposes as indicated is proper. Applicant is

advised that a reply to this restriction requirement must include an election for the invention (i.e. Group 1 or 2 or 3, etc.) to be examined, for the reply to be complete, notwithstanding that the requirement be traversed (37 CFR 1.143). Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if none or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanies by a petition under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Conclusion

Claims 1-59 are subject to a restriction requirement. There are 2256 separate inventions.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ramin (Ray) Akhavan whose telephone number is 571-272-0766. The examiner can normally be reached on Monday- Friday from 8:00-4:30. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Remy Yucel, Ph.D. can be reached on 571-272-0781. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

GERRY LEFFERS
PRIMARY EXAMINER